

Food and Drug Administration New Orleans District Southeast Region 6600 Plaza Drive, Suite 400 New Orleans, Louisiana 70127

Telephone: 504-253-4519 Facsimile: 504-253-4520

August 23, 2001

WARNING LETTER NO. 2001-NOL-49

FEDERAL EXPRESS OVERNIGHT DELIVERY

Mr. Richard M. Durrett, Owner Simmesport Fish Company 168 Riverfront Drive Simmesport, Louisiana 71369

Dear Mr. Durrett:

We inspected your firm, located at 168 Riverfront Drive, Simmesport, Louisiana, on June 21, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, Code of Federal Regulations (CFR), Part 123 and of the Current Good Manufacturing Practice regulations, 21 CFR, Part 110. These deviations cause your freshwater fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations are as follows:

You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces with sufficient frequency to ensure control as evidenced by:

- Pitted and nicked cutting board surfaces encrusted with a brown and gray residue from previous operations;
- Metal parts of a brace holding the cutting boards were rusted; and,
- Knives and hatchets stored in rusted metal rack.

During the inspection, our investigator documented numerous insanitary conditions. The inspection found employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of those items from microorganisms or foreign substances. For example:

- An employee retrieved processed fish from the floor, rinsed them with water, and returned them to production; and,
- Employees placed perforated containers, filled with processed fish, directly on the wet floor.

Cleaning and sanitizing utensils and equipment are not conducted in a manner that protects food and food contact surfaces from contamination. For example, processing equipment and utensils are washed once a week, rather than on a more frequent basis.

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. For example, numerous flies were observed landing on fish waste and other potential sources of contaminants. Flies also were observed throughout the processing area, directly on equipment and on unprocessed and processed fish.

In addition, our investigator documented conditions that facilitate unsanitary operations that are associated with the construction and design of your facility. For example:

- Doors leading into the processing facility do not completely close, resulting in a gap between the doors, and providing a potential entry route for pests to enter the processing areas from outdoors;
- Water dripped from the slimy wooden door frame of the cooler directly onto ice that was subsequently placed on processed fish;
- Stagnant water, adjacent to and outside the west wall of the plant, provides a potential reservoir of pathogens and attracts flies and other pests;
- Peeling paint was observed on the ceiling above the processing tables;
- Wooden-handled knives are used for processing fish; and,
- A hatchet, with a dirty string wrapped around the handle, was used to process fish.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that at the close of your inspection, on June 21, 2001, you made a verbal commitment to correct observed deficiencies. We are also aware that you filled a hole in the west wall of the facility during the inspection.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as your sanitation records or other useful information that would assist us

in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Carl E. Draper District Director

New Orleans District

Carl E. Draper

Enclosure: FDA Form 483